DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 18, 2014

Amedica Corporation
Mr. William D. Jordan
Senior Director, Regulatory Affairs & Quality Assurance
1885 West 2100 South
Salt Lake City, Utah 84119

Re: K142347
Trade/Device Name: Valeo II Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP
Dated: September 16, 2014
Received: September 17, 2014

Dear Mr. Jordan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142347

Device Name
Valeo II Interbody Fusion Device

Indications for Use *(Describe)*
Valeo II Interbody Fusion Devices - Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo II Interbody Fusion Devices-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Valeo II Interbody Fusion Devices-Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo II Interbody Fusion Devices-Lumbar are indicated for use with autograft bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Valeo II Interbody Fusion Devices-Lumbar are intended to be used with supplemental spinal fixation systems, such as the Preference Pedicle Screw System. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: August 20, 2014

Contact:
William D. Jordan
Amedica Corp.
1885 West 2100 South
Salt Lake City, UT 84119
Office: (801) 839-3562

Device Trade Name: Valeo II Interbody Fusion Device

Manufacturer:
Amedica Corp.
1885 West 2100 South
Salt Lake City, UT 84119

Common Name: Intervertebral body fusion device

Classification: 21 CFR §888.3080

Class: II

Product Code: MAX, ODP

Indications For Use:

Valeo II Interbody Fusion Devices - Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo II Interbody Fusion Devices-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Valeo II Interbody Fusion Devices-Cervical are to used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo II Interbody Fusion Devices-Lumbar are indicated for use with autograft bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Valeo II Interbody Fusion Devices-Lumbar are intended to be used with supplemental spinal fixation systems, such as Preference Pedicle Screw System. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Device Description:

The Valeo II Interbody Fusion Device consists of a variety of hollow vertebral body spacers featuring convex, bullet nose design and an axial void designed to hold bone graft material. The subject device is offered in various lengths. The subject devices are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 5mm to 22mm in height and 14mm to 34mm in length.

Predicate Device(s):

Primary Predicate Device: Phantom Plus Ceramic Cage System K121892

Performance Testing:

The material change is supported by testing which demonstrates that the proposed device meets the same performance requirements as the predicate device and raises no new concerns with respect to biocompatibility.

Nonclinical testing performed: ASTM F2077-11

Test	Results
Static compression	Pass
Dynamic compression	Pass
Static Torsion	Pass
Dynamic Torsion	Pass

Biocompatibility: ISO 10993 -1: 2009

Standard	Test	Results
ISO 10993-5:2009	Cytotoxicity (MEM/ISO Elution Test)	Pass
ISO 10993-5:2009	Neural Cytotoxicity (MEM/ISO Elution Test	Pass
ISO 10993-10:2010	Maximization Sensitization	Pass
ISO 10993-10:2010	ISO Intracutaneous Irritation Study in Rabbits	Pass
ISO 10993-11:2006	Mutagenicity ISO Systemic Toxicity Study in Mice	Pass
ISO 10993-3:2003	Bacterial Reverse Mutation	Pass
ISO 10993-3:2003	Genotoxicity (Mouse Lymphoma)	Pass
ISO 10993-3:2003	Mouse Peripheral Blood Micronucleus Study	Pass

Guidance Referenced

Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Body Fusion Device

Conclusion

The Valeo II Interbody Fusion device has the same intended use, comparable performance, and is manufactured using similar processes. Performance testing and biocompatibility evaluation demonstrate that the Valeo II Interbody Fusion Device is substantially equivalent to the predicate device.